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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/987,687	11/15/2001	Matthew C. Coffey	032775-078	7186

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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 02/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/987,687	COFFEY ET AL.	
	Examiner	Art Unit	
	J Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1 136(a) In no event however may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication
- If the period for reply specified above is less than thirty (30) days a reply within the statutory minimum of thirty (30) days will be considered timely
- If NO period for reply is specified above the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will by statute cause the application to become ABANDONED (35 U S C § 133)
- Any reply received by the Office later than three months after the mailing date of this communication even if timely filed may reduce any earned patent term adjustment See 37 CFR 1 704(b)

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17 2(a))

* See the attached detailed Office action for a list of the certified copies not received

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U S C § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U S C §§ 120 and/or 121

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson s Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4
4) ☐ Interview Summary (PTO-413) Paper No(s) _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other

DETAILED

Claims 1-21 are pending in the application.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6, 8, 9, 13-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (WO 99/08692).

Lee et al. teaches a method for delivering a reovirus serotype 3 Daring strain virus to a solid tumor to reduce growth of the tumor, comprising administering an effective amount of virus to a subject bearing the tumor, wherein the virus is capable of selectively killing tumor cells, by a base administration selected from the group consisting of:

(a) delivering a composition comprising the virus to multiple sites inside the tumor; and

(b) delivering directly into the tumor a composition comprising the virus, wherein the volume of the composition is between about 10% and 100% of the volume of the tumor (see for instance, abstract; p.3 lines 1-15; p.9, lines17-20; p.34, lines 9-17; Examples 9 and 10; and Claim 38).

Specifically, Lee et al. teaches that after tumor establishment, test animals were treated with a series of six injections over a nine-day course, which constitutes delivering the virus composition to multiple sites inside the tumor (see p. 34, lines 9-17). Lee et al. also teaches

injection of 20µl of Dearing strain reovirus was injected into palpable tumors (see p. 26, lines 16-19). Palpable tumors were defined as having a mean area of $0.31cm^2$ (see page 25, lines 24-25). Therefore injection on 20µl into a palpable tumor with an area of $0.31cm^2$ (.31cc=310µl) constitutes delivering 6.45% (about 10%) of the volume of the tumor.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lorence et al. (WO 94/25627).

Lorence teaches a method for delivering a Newcastle Disease Virus (NDV) or other paramyxovirus to a solid tumor to reduce growth of the tumor, comprising administering an effective amount of virus to a subject bearing the tumor, wherein the virus is capable of selectively killing tumor cells (for example, see p. 3, lines 32-35; p. 4, lines 1-3; p. 11, lines 20-37).

Lorence does not specifically teach that the virus composition is delivered to multiple sites within the tumor or that the volume of the virus composition is between about 10% and 1000% of the volume of the tumor.

However, Lorence does specifically teach, "Effective dosages and schedules for administering the virus may be determined empirically, and making such determinations is within the skill of the art" (see p. 11, lines 26-31).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of invention to create a method of delivering a Newcastle Disease Virus or another type of virus wherein the virus composition is delivered to multiple sites within the tumor and wherein the volume of the virus composition is between about 10% and 100% of the tumor volume. The motivation to do so would have been to devise the most effective dosage and schedule for administering the virus, as mentioned by Lorence (see p. 11, lines 26-31).

5. Claims 10-12 rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (U.S. Patent 6,110,461).

Lee et al. teaches a method for delivering a reovirus serotype 3 Daring strain virus to a solid tumor to reduce growth of the tumor, comprising administering an effective amount of virus to a subject bearing the tumor, wherein the virus is capable of selectively killing tumor cells, by a base administration selected from the group consisting of:

(a) delivering a composition comprising the virus to multiple sites inside the tumor; and

(b) delivering directly into the tumor a composition comprising the virus, wherein the volume of the composition is between about 10% and 100% of the volume of the tumor (see for instance, abstract; p.3 lines 1-15; p.9, lines17-20; p.34, lines 9-17; Examples 9 and 10; and Claim 38).

Specifically, Lee et al. teaches that after tumor establishment, test animals were treated with a series of six injections over a nine-day course, which constitutes delivering the virus composition to multiple sites inside the tumor (see p. 34, lines 9-17). Lee et al, also teaches injection of 20μl of Dearing strain reovirus was injected into palpable tumors (see p. 26, lines 16-19). Palpable tumors were defined as having a mean area of $0.31cm^2$ (see page 25, lines 24-25). Therefore, injection on 20μl into a palpable tumor with an area of $0.31cm^2$ (.31cc=310μl) constitutes delivering 6.45% (about 10%) of the volume of the tumor.

It would have been prima facie obvious to perform routine optimization, as noted in *In re Aller*, 105 USPQ 233 at 235,

> More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the methods of delivering the vector, including volume and number of injections was other than routine, that the effects resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell
February 25, 2002

JEFFREY FREDMAN
PRIMARY EXAMINER